MAR - 1 2004

APPENDIX I SUMMARY OF SAFETY AND EFFECTIVENESS

For

Modified KMI Kompressor Compression Screw System

K040356

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1. **Submitter:**

Kinetikos Medical, Inc.
6005 Hidden Valley Rd. Suite 180
Carlsbad, CA 92009

Contact Person:
John G. Spampinato
V.P., Quality Assurance
Kinetikos Medical, Inc.
6005 Hidden Valley Road Suite 180
Carlsbad, CA 92009
(760) 448 1706 FAX (760) 448 1739

Date Prepared: Feb 10, 2004

2. **Trade Name:** Kompressor Compression Screw System
   Common Name: Compression Screw
   Classification Name: Orthopedic

3. **Predicate or legally marketed devices which are substantially equivalent**

-KMI Kompressor compression screw (K024233)

4. **Description of Device**

The Kompressor bone screw implant is a two-piece fixation device intended for use in the reduction, stabilization, and internal fixation of small bone fractures. The 2-piece design incorporates the use of a leading and trailing screw component. The implant utilizes a variance in thread pitch between the leading and trailing portions of the screw to reduce and fix fracture fragments, and is available in a variety of sizes to accommodate various fracture types and sites.

Materials: Titanium; Ti-6A14V-ELI per ASTM F136

Function: The system functions to draw bone fractures together, thereby facilitating fixation.

5. **Intended Use**

The use of the Kompressor compression screw is generally indicated for the reduction and fixation of fractures appropriate for the size of the device. It is indicated for use in the internal fixation of fractures, fusion, and revision. It is also indicated for reconstructive procedures where reduction and fixation of bone fragments is required (e.g. osteotomies). Contraindications would include any conditions which would contraindicate implants in general, including:

- Infection
- Metal sensitivity or allergic reaction to foreign bodies
- Any concomitant disease which may compromise the function of the implant
- In those cases where avascular necrosis has rendered bone stock inadequate

6. **Comparison of technological characteristics of the device to predicate and legally marketed devices:**

There are no significant differences between the modified Kompressor Compression Screw and the predicate device or other systems currently being marketed which would adversely affect the use of the product. The modified Kompressor compression screw system employs the same mechanical features as the predicate, legally marketed device in that the essential configuration consists of a leading, self-tapping thread and a trailing thread, the varying ratios of which result in the desired compression of the fractured bone segments. Changes were limited to: a new range of sizes and the indications for use have been broadened to include applications other than small bones of the hand and wrist.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2004

Mr. John Spampinato
Vice President, Quality Assurance
Kinetikos Medical, Inc.
6005 Hidden Valley Road, Suite 180
Carlsbad, California 92009

Re: K040356
Trade/Device Name: Kompressor Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 10, 2004
Received: February 17, 2004

Dear Mr. Spampinato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k) Notification - Kompressor Compression Screw System

K040356

Device Name: Kompressor Compression Screw System

Indications for Use:

The use of the Kompressor compression screw is generally indicated for the reduction and fixation of fractures appropriate for the size of the device. It is indicated for use in the internal fixation of fractures, fusion, and revision. It is also indicated for reconstructive procedures where reduction and fixation of bone fragments is required (e.g. osteotomies). Contraindications would include any conditions which would contraindicate implants in general, including:

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONITNUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X Miriam C. Provost OR Over-the-Counter Use _____

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K040356